IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Pellet and Sanchez-Martinez

Patent No. 6,126,944

Filed: June 7, 1995

Confirmation No. 9684

FILED VIA EFS September 19, 2011

For: BACULOVIRU

BACULOVIRUS EXPRESSION VECTORS

AND RECOMBINANT ANTIGENS FOR

DETECTING TYPE-SPECIFIC

ANTIBODIES TO HERPES SIMPLEX

VIRUS

Examiner: Kenya A. McLaughlin

Art Unit: 1623

Attorney Reference No. 6395-87124-02

SUBMITTED VIA THE ELECTRONIC FILING SYSTEM (EFS) COMMISSIONER FOR PATENTS

RESPONSE TO REQUEST FOR INFORMATION

This responds to the Request for Information, dated July 18, 2011, for which a two month period for reply was set, making this response due on or before September 18, 2011, which is a Sunday, making this response due on or before September 19, 2011. Submitted herewith are the following Declarations, with accompanying Exhibits:

- 1. Declaration of Veronica Brown
- 2. Declaration of Sharon Shropshire
- 3. Declaration of Cynthia Sherwood
- 4. Declaration of Francisco Candal
- 5. Declaration of Suzanne Shope
- 6. Declaration of Valentin Fikovsky
- 7. Declaration of Gwendolyn Spratt.

These Declarations establish that the CDC has successfully and timely paid maintenance fees on its patents since the CDC Technology Transfer Office (TTO) was established in 1986. The system in place for the timely tracking and payment of these fees is that the CDC has relied on

the CDC's outside firms to track the payment dates, notify CDC that the fees were due, obtain instructions and funding authorization from CDC for the payment of the fees, and pay the fees. However, the maintenance fee for U.S. Patent No. 6,126,944 was due no later than October 3, 2008 during a time of transition of the file from the CDC's prior law firm (Needle & Rosenberg). Hundreds of files were being transferred in 2007-2008, during which there was also a transition of personnel at the CDC TTO who were responsible for the '944 patent. It was the understanding of all personnel at CDC that in 2007 only inactive files would be sent directly to CDC instead of to one of the CDC's law firms. During this period of transition, the file for U.S. Patent No. 6,126,944 was sent by Needle & Rosenberg directly to the CDC, and personnel at CDC did not realize that an active file requiring action had been sent to them. The file was therefore diverted from the tracking and payment system that had functioned so well since 1986, and the fee was not timely paid by the October 3, 2008 deadline.

Petitioner has also provided a Declaration of Gwen Spratt, who was the attorney at Needle & Rosenberg (later Ballard Spahr) who was responsible for CDC matters at that firm. According to her Declaration, it was her understanding in 2006 that the general procedure for transferring CDC files was for active files to be transferred directly from her firm to the CDC's new patent prosecution firms. Many active files were directly transferred to the new firms under this policy, however her firm retained many inactive files awaiting instructions about how to proceed. By late 2007 her firm had many inactive files in its possession and a few active files. Since her firm's patent services contract had expired and funding for prosecuting them had been depleted, and it was unclear to her at that time what the CDC policy was with respect to where active files should be shipped, a mixture of inactive and active files were boxed and sent directly to CDC in September and November 2007.

Hence the cause of delay in paying the maintenance fee by the surcharge date is that the file was not shipped directly from Needle & Rosenberg directly to one of the CDC's patent prosecution firms. This mistake was the result of a misunderstanding between CDC personnel and Needle & Rosenberg about file transfer procedures. CDC personnel understood that only active files were being transferred directly to CDC and did not review the contents of the boxes that were shipped directly to them from Needle & Rosenberg.

The CDC TTO received a Notice of Expiration of U.S. Patent No. 6,126,944 on November 28, 2008, the day after Thanksgiving. Through a docketing error on the part of Veronica Brown,

the Notice of Expiration was not entered into the calendaring system and it therefore did not subsequently come to the attention of the CDC that the patent had expired. Personnel at CDC did not track and pay maintenance fees because that was a function that had been delegated to its outside law firms. Valentin Fikovsky, the Patent Advisor at CDC for U.S. Patent No. 6,126,944, believed that any active file would have been on the docket of one of the CDC's contracted law firms, and therefore expected that one of the firms would have tracked any deadlines and contacted him about any action that was required to revive it.

The system under which the CDC's outside law firms had successfully tracked and paid maintenance fees had operated well since 1986. Maintenance fees had been timely paid on all CDC patents since the CDC TTO was opened in 1986 until 2008. The non-payment of the fee for U.S. Patent No. 6,126,944 (along with the non-payment of related U.S. Patent No. 6,013,433) are believed to be the first instances in which a CDC maintenance fee that was to be paid was not tracked and timely paid. This unavoidable oversight was entirely due to the unusual circumstances of the file being sent directly to CDC TTO instead of one of the CDC's contract law firms, at a time when hundreds of files were being transferred from the CDC's prior firm. This transfer of hundreds of files, the presence of the file for U.S. Patent No. 6,126,944 in a box of files that CDC thought were inactive, and the clerical error calendaring the Notice of Expiration resulted in the nonpayment of the fee.

The following points are addressed by the specific Declarations in response to questions raised by the Petitions Attorney.

- I. Petitioner was requested to address the delay in paying the maintenance fee aside from the file erroneously sent to the assignee, such as by providing statements from individual charged with paying the maintenance fee. In this regard, Petitioner was requested to obtain statements from persons at Needle & Rosenberg who may have firsthand knowledge about the file transfer. Petitioner was requested to determine if there was a clerical error at Needle & Rosenberg.
- A. Counsel for the petitioner contacted a representative (Sumner Rosenberg, Managing Partner, Atlanta Office) of Ballard Spahr on August 16, 2011 to obtain copies of all correspondence related to their transfer of U.S. Patent No. 6,126,944. Mr. Rosenberg provided

all documentation available at Ballard Spar relating to the transfer of this file. A complete copy of this documentation is provided as Exhibit E accompanying the Declaration of Francisco J. Candal.

It was determined that the file was transferred on September 28, 2007, which was prior to the initial due date for paying the maintenance fee. Thus, the delay in paying the maintenance fee could not have been due to clerical error at Needle & Rosenberg.

However, Petitioner has obtained a Declaration of Gwen Spratt that describes Needle & Rosenberg's file transfer policy.

B. The Declaration of Valentin Fikovsky submitted on May 27, 2011 provides information on the file transfers that occurred under the patent services contract. As stated by Mr. Fikovsky, on September 1, 2006, the CDC awarded a new seven-year patent services contract to two law firms. These two firms were Klarquist Sparkman LLP (hereinafter "Klarquist Sparkman") and Gifford, Krass, Sprinkle, Anderson & Citowski, P.C. (hereinafter "Gifford Krass"). As Needle & Rosenberg was no longer a designated contract law firm for the CDC, Needle & Rosenberg began transferring the active files to the new contract attorneys, Klarquist Sparkman and Gifford Krass at the request of the CDC in 2006. Mr. Fikovsky stated that Needle & Rosenberg shipped to Klarquist Sparkman approximately 142 files related to seventeen different technologies that had been and were being prosecuted in the United States and many corresponding foreign countries. Needle & Rosenberg shipped to Gifford Krass approximately 60 files related to ten different technologies.

According to CDC procedures in 2007, files for patents and applications that were in active prosecution or required other action (such as payment of maintenance fees) were to be sent from Needle & Rosenberg directly to one of the two law firms awarded the new patent services contract. Files for expired patents and abandoned patent applications were to be shipped from Needle & Rosenberg directly to the CDC for storage at the CDC Technology Transfer Office in Atlanta, Ga. However, the transfers occurred over an extended period of time as funds already obligated to Needle & Rosenberg under the prior contact were depleted. Thus, Needle &

Page 4 of 8

¹ The second maintenance fee could have been paid from October 3, 2001 through April 3, 2008, or with a surcharge, as authorized by 37 C.F.R. § 1.20(h) during the period from April 4, 2008 to October 3, 2008. This information is provided on page 1 in the Request for Information.

Rosenberg remained responsible for U.S. Patent No. 6,129,944 until the obligated funds for that matter were depleted.

An error was identified in the transfer process for this file. It was the policy of CDC TTO in 2007 that files for patents and applications that were in active prosecution or required other action (such as payment of maintenance fees) would be transferred from Needle & Rosenberg directly to one of the two new law firms the CDC had contracted with to handle patent prosecution. Although CDC TTO personnel understood this to be the procedure, no documents have been located that confirmed that policy with Needle & Rosenberg. When undersigned representative for CDC spoke to Gwen Spratt, the partner at Needle & Rosenberg who was responsible for CDC matters at the time of the transfer, she indicated that in 2006 she understood that the general CDC policy would be to transfer active files to the CDC's new patent prosecution firms. However, by late 2007 her firm still retained many accumulated inactive CDC files and a few active files, and at that time all those remaining CDC files were boxed and shipped directly to CDC. Therefore, there was a miscommunication between CDC and Needle & Rosenberg with respect to this policy. Files for non-expired patents and abandoned patent applications were therefore shipped from Needle & Rosenberg directly to the CDC Technology Transfer Office in Atlanta, Ga. A list of all "active" files and a list of all "inactive" files that were at Needle & Rosenberg, and were ready to be shipped, were emailed to the CDC. However, as it was the understanding of personnel at CDC that all active files were to be transferred to the new law firms, these lists were not reviewed in detail, since it was understood by CDC personnel that only inactive files would be sent to the CDC. A complete explanation of these events is provided in the Declarations of Francisco J. Candal and Gwen Spratt, submitted herewith.

- II. Petitioner is required to explain what procedures, if any, the petitioner had in place for screening the patent files received at the CDC from Needle & Rosenberg.
- A. There were no formal procedures in place at the CDC for screening the transferred files. This is because the Petitioner believed that pursuant to their policy all the transferred files were inactive.
- B. As discussed in the Declaration of Suzanne Seavello Shope, in April 2008 she requested a report from Needle & Rosenberg listing active cases that were still at Needle &

Rosenberg. Listed on this report was one active patent family (I-006-97/0) that was incorrectly sent to the CDC. When the error was identified, the files were immediately transferred to Klarquist Sparkman. However, the April 2008 report of active cases did not include CDC's matter E-021-91 (U.S. Patent No. 6,126,944); had that file been listed on the list of active cases at that time the CDC would have instructed the transfer of the file to one of its patent firms.

- III. Petitioner was requested to explain how the delay between receiving the Notice of Patent Expiration, sent to the CDC by Needle & Rosenberg on November 20, 2008 and the filing of the original petition in May 2011 was unavoidable.
 - A. Due to a clerical error, the Notice of Expiration was never entered into the CDC's electronic database (see MPEP §711.03(c)(2)).
 - 1. The Declaration of Ms. Shropshire states that she was responsible for receiving patent office correspondence. Pursuant to CDC procedures, the CDC Management and Program Analyst, Ms. Veronica Brown, was supposed to enter all relevant deadlines in the electronic database. However, as a result of a clerical error, Ms. Brown did not enter the Notice of Expiration into the CDC TTO Inteum database. Since Ms. Brown did not calendar any due dates related to the Notice of Expiration the expired status of the patent was not reflected in the CDC's electronic database.
 - 2. The Declaration of Mr. Candal states that since this matter was not on his docket, he forwarded the Notice of Patent Expiration to the other Patent Advisor, Mr. Valentin Fikovsky, and the Technology Licensing and Marketing Scientists, as well as to Ms. Sherwood.
 - 3. The Declaration of Ms. Sherwood, Ms. Brown's supervisor, states that although Ms. Sherwood received the correspondence, she believed it had already been entered into the database by Ms. Brown, pursuant to the procedures at the CDC.
 - 4. Mr. Fikovsky's Declaration provides additional information on why it was believed the Notice was entered into the CDC electronic database. As stated in Mr. Fikovsky's declaration, this matter did not come to his attention again until April 13, 2011 when a search in PAIR was performed solely to determine the patent term of U.S. Patent No. 6,126,944 in order to determine how long the CDC

Page 6 of 8

would continue to collect royalties on the licenses for this patent. Once it was identified that the second maintenance fee was never paid, action was taken immediately.

The docketing error was the cause of the delay in taking action in response to the Notice of Expiration. As illustrated by the attached Declaration, there was a procedure in place for performing the entry of this information into the Inteum database. The entry of the information was performed by an experienced CDC employee (Veronica Brown) who had been at the CDC for at least 5 years, and who was being supervised by an experienced patent paralegal and supervisor (Cynthia Sherwood). These employees were sufficiently trained and experienced that it represented the exercise of due care for the CDC TTO to rely upon these employees in the performance of their duties.

IV. Summary

The Declarations provide evidence that there were systems in place at the CDC for tracking and payment of patent maintenance fees by the CDC's outside law firms. Over a period of years, many maintenance fees were successfully tracked and paid under these procedures, and the declarants state their belief that U.S. Patent No. 6,126,944 (and related U.S. Patent No. 6,013,433) are the first instances in which a CDC patent expired when such expiration was not desired. The CDC therefore exercised due care in justifiably relying on these procedures.

As documented in the Declarations, non-payment of the maintenance fee occurred at a time when hundreds of files were being transferred from the CDC's prior counsel to its new firms. It was the understanding of personnel at CDC that in 2007 only inactive files were being transferred directly to CDC, and any active files were to be sent directly one of the CDC's other patent firms. As a result, when a box containing U.S. Patent No. 6,126,944 was sent directly to CDC it was not reviewed because personnel at CDC thought the box would only contain inactive files. Correspondence about the files that accompanied the box was similarly not reviewed. A subsequent Notice of Expiration that was received by the CDC on the day after Thanksgiving was not entered due to a clerical error by a patent program specialist (Veronica Brown) who was being supervised by an experienced supervisor (Cynthia Sherwood). Thus, the expired status of the patent was not entered in the electronic database so that they could be tracked by a Patent

Advisor. The Petitioner therefore did not file a request to revive this patent at the time the patent expired. The docketing error was only identified during a routine review to determine the term of the patent. Once the expiration of this patent was identified, the Petitioner acted expeditiously, and filed a Petition to Revive this patent on May 27, 2011.

Petitioner requests that the Petition to Revive be granted.

Respectfully submitted,

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